

## REMARKS

Claims 2, 4, 6, and 8-12 were previously canceled. Claim 5 has been amended. Claims 1, 3, 5, 7, 13, 14 and 15 remain in the application. Support for the amendment to claim 5 can be found in the specification at least on page 3, lines 16-18; and page 4, lines 24-26 and 33-34. No new matter has been added. This application has been carefully considered in connection with the Examiner's Action. Reconsideration, withdrawal of the final action, and allowance of the application, as amended, is respectfully requested.

### **Rejection under 35 U.S.C. §103**

Claim 1 recites a medical apparatus comprising at least one surface which is at least partially coated with a hydrolytically condensed organosilane sol-gel composition, wherein the organosilane sol-gel composition comprises a mixture of tetraethoxysilane, methyltrimethoxysilane, and organosilane compounds that contain an organic, polymerizable substituent, wherein the organosilane compounds that contain the organic, polymerizable substituent consist of 3-glycidoxypropyl trimethoxysilane, methacryloxypropyl trimethoxysilane and vinyl trimethoxysilane, and wherein the organosilane sol-gel composition is further formed from dimethylmalonic acid.

Claims 1, 3, 5 and 13 to 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Havey et al (US 6,001,163) in view of Clark (US 4,027,073). With respect to claim 1, Applicant respectfully traverses this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness.

As the PTO recognizes in MPEP § 2142:

*... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...*

It is submitted that, in the present case, the examiner has not factually supported a prima facie case of obviousness for at least the following, mutually exclusive, reasons.

**1. Even When Combined, the References Do Not Teach the Claimed Subject Matter**

The **Havey** and **Clark** references cannot be applied to reject claim 1 under 35 U.S.C. § 103 which provides that:

*A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains ...* (Emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, since neither **Havey** nor **Clark** teaches an “organosilane sol-gel composition [*that*] comprises a *mixture* of [(i)] **tetraethoxysilane**, [(ii)] methyltrimethoxysilane, **and** [(iii)] organosilane compounds ... wherein the organosilane compounds that *contain* the organic, polymerizable substituent **consist of** [(iii)(a)] 3-glycidoxypropyl trimethoxysilane, [(iii)(b)] methacryloxypropyl trimethoxysilane and [(iii)(c)] vinyl trimethoxysilane, **and** wherein the organosilane sol-gel composition is further formed from [(iv)] dimethylmalonic acid” [emphasis added] as is specifically claimed in claim 1, it is impossible to render the subject matter of claim 1 as a whole obvious, and the explicit terms of the statute cannot be met. In other words, claim 1 requires elements (i), (ii), (iii), and (iv), and wherein element (iii) consists of (iii)(a), (iii)(b), and (iii)(c). Neither Havey nor Clark teach or suggest the specific organosilane sol-gel composition as is explicitly recited and claimed in claim 1.

Furthermore, while Havey discloses a composition for providing an abrasion resistant coating on a substrate, Havey does not teach use of (a) tetraethoxysilane nor (b) vinyl trimethoxysilane nor (c) dimethylmalonic acid in an organosilane sol-gel

composition as specifically required and recited in claim 1 of the present application. Neither does Havey teach a cured coating that exhibits resistance to iodine staining and cracking.

Thus, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

## 2. The Combination of References is Improper

Assuming, arguendo, that the above argument for non-obviousness does not apply (which is clearly not the case based on the above), there is still another, mutually exclusive, and compelling reason why the **Havey** and **Clark** references cannot be applied to reject claim 1 under 35 U.S.C. § 103.

§ 2142 of the MPEP also provides:

*...the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made.....The examiner must put aside knowledge of the applicant's disclosure, refrain from using hindsight, and consider the subject matter claimed 'as a whole'.*

Here, neither **Havey** nor **Clark** teaches, or even suggests, the desirability of the combination since neither teaches the specific elements of (a) tetraethoxysilane or (b) vinyl trimethoxysilane in an organosilane sol-gel composition as specifically required and recited in claim 1 of the present application. Neither do Havey or Clark teach a coating that exhibits resistance to iodine staining and cracking.

Thus, it is clear that neither patent provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

In this context, the MPEP further provides at § 2143.01:

*The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.*

In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case it is clear that the examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 1. Therefore, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

Accordingly, claim 1 is allowable and an early formal notice thereof is requested. Dependent claims 3 and 5 depend from and further limit independent claim 1 and therefore are allowable as well. The 35 U.S.C. § 103(a) rejection thereof has now been overcome.

Claim 13 has been amended in a similar manner to that of amended claim 1. For at least the same reasons as presented with respect to claim 1 above, claim 13 is believed allowable. Dependent claims 14 and 15 depend from and further limit independent claim 13 and therefore are allowable as well. Accordingly, withdrawal of the rejection and an early formal notice of allowability is respectfully requested.

Claims 1, 3, 5, 7 and 13 to 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schachter (US 2005/0008763) in view of Clark. With respect to claim 1, Applicant respectfully traverses this rejection on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

As the PTO recognizes in MPEP § 2142:

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It is submitted that, in the present case, the examiner has not factually supported a prima facie case of obviousness for at least the following, mutually exclusive, reasons.

**1. Even When Combined, the References Do Not Teach the Claimed Subject Matter**

The **Schachter** and **Clark** references cannot be applied to reject claim 1 under 35 U.S.C. § 103 which provides that:

*A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains ...* (Emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, since neither **Schachter** nor **Clark** teaches an "organosilane sol-gel composition [that] comprises a mixture of [(i)] **tetraethoxysilane**, [(ii)] methyltrimethoxysilane, and [(iii)] organosilane compounds ... wherein the organosilane compounds that contain the organic, polymerizable substituent **consist of** [(iii)(a)] 3-glycidioxypropyl trimethoxysilane, [(iii)(b)] **methacryloxypropyl trimethoxysilane** and [(iii)(c)] vinyl trimethoxysilane, and wherein the organosilane sol-gel composition is further formed from [(iv)] dimethylmalonic acid" [emphasis added] as is specifically claimed in claim 1, it is impossible to render the subject matter of claim 1 as a whole obvious, and the explicit terms of the statute cannot be met. In other words, claim 1 requires elements (i), (ii), (iii), and (iv), and wherein element (iii) consists of (iii)(a), (iii)(b), and (iii)(c). Neither **Schachter** nor **Clark** teach or suggest the specific

organosilane sol-gel composition as is explicitly recited and claimed in claim 1.

Furthermore, while **Schachter** discloses an antimicrobial coating for medical applications, **Schachter** does not teach use of (a) tetraethoxysilane nor (b) methacryloxypropyl trimethoxysilane nor (c) dimethylmalonic acid in an organosilane sol-gel composition as specifically required and recited in claim 1 of the present application. Neither does Schachter teach a cured coating that exhibits resistance to iodine staining and cracking.

Thus, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

## 2. The Combination of References is Improper

Assuming, arguendo, that the above argument for non-obviousness does not apply (which is clearly not the case based on the above), there is still another, mutually exclusive, and compelling reason why the **Schachter** and **Clark** references cannot be applied to reject claim 1 under 35 U.S.C. § 103.

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Here, neither **Schachter** nor **Clark** teaches, or even suggests, the desirability of the combination since neither teaches the specific elements of (a) tetraethoxysilane or (b) methacryloxypropyl trimethoxysilane in an organosilane sol-gel composition as specifically required and recited in claim 1 of the present application. Neither do Schachter or Clark teach a cured coating that exhibits resistance to iodine staining and cracking.

Thus, it is clear that neither patent provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

In this context, the MPEP further provides at § 2143.01:

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In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case it is clear that the examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 1. Therefore, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

Accordingly, claim 1 is allowable and an early formal notice thereof is requested. Dependent claims 3, 5 and 7 depend from and further limit independent claim 1 and therefore are allowable as well. The 35 U.S.C. § 103(a) rejection thereof has now been overcome.

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### **Conclusion**

Except as indicated herein, the claims were not amended in order to address issues of patentability and Applicants respectfully reserve all rights they may have under the Doctrine of Equivalents. Applicants furthermore reserve their right to reintroduce subject matter deleted herein at a later time during the prosecution of this application or a continuation application.

It is clear from all of the foregoing that independent claims 1 and 13 are in condition for allowance. Dependent claims 3, 5 and 7 depend from allowable independent claim 1, and are thus also allowable. Dependent claims 14 and 15 depend from allowable independent claim 13 and are thus also allowable.

Amendments herein are fully supported by the original specification and drawings as discussed herein; therefore, no new matter is introduced. Withdrawal of the final action and issuance of an early formal notice of allowance of claims 1, 3, 5, 7, and 13-15 is requested.

Respectfully submitted,



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